## Fixed Versus Rotating Platform Total Knee Arthroplasty: A Prospective, Randomized, Single-Blind Study

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**Abstract:** The purpose of this randomized, single-blind clinical trial was to compare a rotating platform (RP) total knee arthroplasty to a fixed-bearing (FB) total knee arthroplasty. Ninety-five knees in 69 patients were implanted by 2 surgeons. There were no significant differences in the preoperative demographics. At a minimum of 2-year follow-up, clinical outcomes and complication rates were similar, with the exception that the RP group had significantly better stair-climbing scores (P = .04). Postoperative range of motion was equally good in both groups (FB knees, 1°-125°; RP knees, 1-126°). There were no bearing dislocations in the RP group. In conclusion, this RP design performs at least as well as the FB version, and the RP patients reported better stair-climbing ability. Enthusiasm for this finding should be tempered by the relatively small sample size. **Keywords:** total knee arthroplasty, mobile bearing, rotating platform, high flexion, stair climbing.

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Fixed-bearing (FB) total knee arthroplasties (TKAs) have generally performed well with high clinical success rates and survivorship [1-6]. However, failures can occur as a result of polyethylene wear, osteolysis, and component loosening [7,8]. Rotational constraint of some FB TKAs has been associated with increased torque at the bone-prosthesis interface, which can lead to early loosening [9,10]. Also, this increased torque may be transmitted to the insert-baseplate interface, which can increase back-side wear, osteolysis, and loosening [11-14]. Lower tibiofemoral conformity reduces constraint but results in higher surface contact stresses, which have been associated with subsurface fatigue and delamination of polyethylene sterilized by

© 2011 Elsevier Inc. All rights reserved. 0883-5403/2604-0004\$36.00/0 doi:10.1016/j.arth.2010.06.003 gamma irradiation in air [15,16]. Mobile-bearing TKAs allow a higher degree of tibiofemoral conformity (lower contact stresses) with low rotational constraint but are accompanied by concerns for back-side wear and bearing subluxation or dislocation.

There have been few prospective, randomized clinical trials directly comparing FB and mobile-bearing designs [17-23] and none for this specific device. The goal of the current study was to compare outcomes using the same posterior stabilized (PS) total knee prosthesis with lower sagittal plane conformity (to facilitate deeper flexion), with either a fixed or a rotating platform (RP) tibial bearing. The null hypothesis being tested is that there is no difference in clinical outcomes between the 2 designs in the short term, with particular emphasis on complication rate, range of motion, and extensor mechanism function as tested by the presence of anterior knee pain, the ability to climb stairs, and perform a chair-rise test.

## **Materials and Methods**

Under the auspices of an Food and Drug Administration–approved investigational device exemption (IDE) trial, patients were enrolled into a prospective, randomized, single-blind clinical trial at 2 centers (2 surgeons, TPS and OMM). The study was approved by the institutional review board at both locations, and informed consent was obtained from each patient.

Patients were randomized to receive either the FB, PS Scorpio Total Knee Arthroplasty (Stryker; Mahwah, NJ)

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**Fig. 1.** (A) Scorpio FB tibial component demonstrating peripheral full-capture locking mechanism. (B) Scorpio Plus RP tibial component demonstrating central mushroom-type rotation peg. (C) Scorpio Plus RP tibial component (left) and Scorpio FB tibial component (right). Note: the articular surface geometry of the tibial insert is identical between the devices.

or the RP version of the same PS knee (Scorpio Plus). The Scorpio Plus is not available in the United States. There is no difference in femoral component geometry between designs. The primary difference between implants lies in the tibial insert locking mechanism (Fig. 1A-C). The FB prosthesis has a peripheral locking mechanism, whereas the RP prosthesis is secured to the baseplate with a mushroom-type peg that fastens to the undersurface of the polyethylene bearing. All polyethylene components were machined, sterilized by gamma irradiation in nitrogen, and barrier packaged.

Between November 2001 and March 2005, 100 knees in 74 patients were enrolled in the study. Two patients withdrew from the study, and 3 patients were lost to follow-up. Each of these patients had been randomized to the FB group. In addition, 2 patients with the FB prosthesis underwent revision before their 2-year follow-up. Therefore, 7 patients, all with FB knees, were removed from the minimum 2-year data analysis.

Ninety-three knees in 67 patients were followed clinically and radiographically, for a minimum of 2 years (average, 48 months; range, 24-60 months). Forty-two knees received the FB, PS TKA (control group; 23 TPS, 19

<b>Table 1.</b> Preoperative Demographi
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	FB	Mobile Bearing	Р
Age (y)	64.0	64.9	.55
Sex (M/F)	18:23	22:28	
BMI $(kg/m^2)$	31	31	.52
ROM (degrees)	6-111	7-113	.69
Mechanical alignment	Varus 1.7 ± 8.0	Varus 2.0 ± 7.0	.80
(degrees)			
KSS Clinical	$34.5 \pm 12.6$	31.7 ± 12.75	.31
KSS Functional	$45.7 \pm 8.8$	$46.3 \pm 6.7$	.73
KSS Stairs	$28.9 \pm 5.1$	$30.1 \pm 2.9$	.17
SF-12 Physical	$32.0 \pm 7.4$	$30.6 \pm 8.1$	.39
SF-12 Mental	$45.3 \pm 11.9$	$46.9 \pm 12.6$	.55

BMI indicates body mass index; ROM, range of motion; KSS, Knee Society score.

OMM) and 51 knees received the RP, PS TKA (study group; 28 TPS, 23 OMM). There were no significant preoperative differences between the groups (Table 1).

One surgeon (TPS) exposed the knee through a medial parapatellar approach, whereas the other surgeon (OMM) used a subvastus approach. If any lateral subluxation or tilt was present, the lateral retinaculum was released until central patellar tracking was obtained. Closed-drain suction was used in all cases. Inpatient continuous passive motion was used by one surgeon (OMM). Otherwise, perioperative rehabilitation protocols were similar between surgeons.

Radiographs were obtained and reviewed, and clinical outcomes were assessed at 7 weeks, 6 months, 1 year, and annually thereafter with the Knee Society (KS) score and the 12-item Short-Form Health Survey (SF-12) physical and mental assessments [24,25]. These outcomes questionnaires were given to the patient who answered the questions independent of the practitioner. The patients were blinded to the type of prosthesis that they received. The physical examination and radiographic review were performed by the treating surgeon at each follow-up visit. The surgeons were not blinded to the type of prosthesis. Extensor mechanism function was assessed using the stair-climbing component of the KS function score, a chair-rise test, and the presence or absence of anterior knee pain [26].

Statistical comparisons were done using Student 2tailed *t* test,  $\chi^2$  test, and linear regression for correlations. Data were analyzed using SPSS 11.5 statistical analysis software (SPSS, Chicago, Ill) and/or STATA 5.0 (STATA, College Station, Tex). Because the 2 participating centers in the current study were part of a larger, Food and Drug Administration–approved, IDE trial, a separate, post hoc power analysis was performed specifically evaluating the study design within these 2 centers. With 100 patients enrolled and a medium effect size [27] of 0.5, the current study achieves a statistical power of 0.80. Using the data recorded in the current study, an effect size of 0.5 Download English Version:

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